

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC.,)
PAR STERILE PRODUCTS, LLC, and)
ENDO PAR INNOVATION)
COMPANY, LLC,)
Plaintiffs,) C.A. No. 18-823-CFC
v.)) **CONFIDENTIAL-**
EAGLE PHARMACEUTICALS INC.,) **FILED UNDER SEAL**
Defendant.)

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO
DISMISS THE FIRST, SECOND, SEVENTH,
EIGHTH, ELEVENTH, TWELFTH AND SIXTEENTH
COUNTERCLAIMS OF EAGLE PHARMACEUTICALS, INC.'S
FIRST AMENDED ANSWER TO COMPLAINT AND COUNTERCLAIMS**

Dated: November 20, 2019

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Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively, “Par”) hereby move, pursuant to Fed. R. Civ. P. 12(b)(1), to dismiss the First, Second, Seventh, Eighth, Eleventh, Twelfth and Sixteenth Counterclaims of Eagle’s First Amended Answer to Complaint and Counterclaims, in which Eagle seeks declaratory judgments of invalidity, non-infringement, and unenforceability of patents that Par is no longer asserting in this matter (U.S. Pat. Nos. 9,375,478, 9,744,239 and 9,937,223 (the “Dropped Patents”)). Because Par is no longer asserting any claim for infringement of the Dropped Patents, and has agreed to dismiss its claims for infringement of the Dropped Patents with prejudice, there is no justiciable controversy between Par and Eagle with respect to the infringement, validity, or enforceability of the Dropped Patents. Accordingly, the Court should dismiss Eagle’s First, Second, Seventh, Eighth, Eleventh, Twelfth and Sixteenth Counterclaims (the “Mooted Counterclaims”) as moot, without prejudice.

I. FACTUAL AND PROCEDURAL BACKGROUND

Par filed this patent infringement action on May 31, 2018. It seeks injunctive and other relief arising from Eagle’s submission of an Abbreviated New Drug Application (“ANDA”) seeking FDA approval to market a generic version of Par’s VASOSTRICT® products. D.I. 1. Par initially asserted infringement of six patents—Nos. 9,375,478 (the ’478 Patent), 9,687,526 (the ’526 Patent), 9,744,209

(the '209 Patent), 9,744,239 (the '239 Patent), 9,750,785 (the '785 Patent), 9,937,223 (the '223 Patent). *Id.* at ¶ 5. Through the course of discovery, Par has narrowed its asserted claims, and now only asserts claims for infringement of the '526, '209 and '785 Patents.

In particular, on August 26, 2019, Par served an amended disclosure of asserted claims, advising Eagle that it was no longer asserting any claim for infringement of the '239 Patent. *See* Ex. A, ¶4.¹ At that time, Eagle still had not produced all documentation relating to the stability and other characteristics of its accused ANDA product, and Par had not taken any depositions of Eagle or the supplier of its ANDA product. Gagliardi Decl. ¶ 4. Accordingly, Par informed Eagle at that time that it expected to further narrow the list of asserted claims after completing that pending discovery. *Id.*

Several days later, Eagle requested that Par stipulate to the dismissal with prejudice of its claim for infringement of the '239 Patent. Ex. B at 1-2. Par promptly provided a proposed stipulation in response to that request, pursuant to which its claim for infringement of the '239 Patent would be dismissed with prejudice, and Eagle's corresponding counterclaims for non-infringement and invalidity of the '239 Patent would be dismissed without prejudice as moot. Ex. B

¹ All lettered exhibits refer to attachments to the November 20, 2019 Declaration of Sharon K. Gagliardi being filed herewith ("Gagliardi Decl.").

(e-mail with attachment). Despite Par having raised the issue on multiple occasions, Eagle has never responded substantively to Par's proposal in the two and a half months since Par provided Eagle with the proposed stipulation it requested. Gagliardi Decl. ¶ 6.

On October 16, 2019, pursuant to Paragraph 3(a)(vi) of the Court's Scheduling Order (D.I. 20, 117), Par submitted its final disclosure of asserted claims and infringement contentions to Eagle, in which Par dropped its contentions relating to the '478 and '223 Patents, and advised Eagle that Par was no longer asserting claims for infringement of those patents as well. *See* Ex. C. Thereafter, Par offered to stipulate to the dismissal with prejudice of its counts for infringement of those patents, but Eagle has likewise not yet responded substantively to that proposal. Ex. D at 1; Gagliardi Decl. ¶¶ 6, 10.

On October 30, 2019, Eagle filed its First Amended Answer to Complaint & Counterclaims, asserting counterclaims relating to the Dropped Patents, despite knowing that Par is no longer asserting any claims against it with respect to those Patents. D.I. 136. In particular, Eagle asserted Counterclaims for declaratory judgment of non-infringement and invalidity of the '478 Patent (First and Second Counterclaims), the '239 Patent (Seventh and Eighth Counterclaims) and the '223 Patent (Eleventh and Twelfth Counterclaims), as well as a Counterclaim for unenforceability of the '239 Patent (Sixteenth Counterclaim).

The deadline for serving initial expert reports on issues for which a party bears the burden of proof was November 15, 2019. D.I. 116. Eagle served expert reports regarding the alleged invalidity and unenforceability of the '526, '209, '785 and '239 Patents, but did not serve any expert reports relating to the '478 or '223 Patents (*i.e.*, relating to two of the three Dropped Patents). Gagliardi Decl. ¶ 9. Notwithstanding the fact that Eagle has apparently decided that it no longer seeks a declaration of invalidity or unenforceability with respect to at least the '478 and '223 Patents (*i.e.*, two of the three Dropped Patents), counsel for Eagle emailed Par on November 18, 2019 stating that they were still conferring with Eagle regarding Par's proposed stipulations of dismissal with respect to those Patents, and that they would respond further at an unspecified date in the future. *Id.* ¶ 10.

II. ARGUMENT

A. The Court Should Dismiss the Mooted Counterclaims for Lack of a Justiciable Case or Controversy

It is well-established that a declaratory judgment plaintiff has the burden of showing that there exists “a substantial controversy” that is “of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1281-82 (Fed. Cir. 2012) (quoting *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007)); *see also* 28 U.S.C. § 2201(a). In patent cases, the declaratory judgment plaintiffs must show that this actual “case or controversy” exists with respect to

each patent claim for which they seek a declaratory judgment of non-infringement, invalidity, or unenforceability. *See Streck*, 665 F.3d at 1281 (citing *Jervis B. Webb Co. v. So. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984)); *Benitec*, 495 F.3d at 1343 (noting that declaratory judgment plaintiff has the burden of showing there is a substantial controversy for all of its claims). That burden applies not only at the time when the declaratory judgment counterclaim is initially filed, but also throughout all stages of the case. *Streck*, 665 F.3d at 1282.

Of particular relevance here, the Federal Circuit made clear in *Streck* that even where a patentee initially asserts infringement of particular patent claims, and thereafter withdraws some but not all of them, “a counterclaimant must show a continuing case or controversy with respect to withdrawn or otherwise unasserted claims.” *Id.* at 1283. Eagle cannot meet that burden with respect to the Dropped Patents. Par no longer asserts claims for infringement of the Dropped Patents and has offered to have those claims dismissed with prejudice.² Eagle cannot establish that there remains any justiciable case or controversy between the parties as to those Patents. *See, e.g., Streck*, 665 F.3d at 1283-84 (affirming district court’s finding of no case or controversy over claims that the patentee was no longer

² As noted above, to date, Eagle has not substantively responded to Par’s offers to enter into a stipulation dismissing its claims for infringement of the Dropped Patents and has provided no explanation of why it has been unable to or otherwise refuses to do so.

asserting in the case); *Fox Grp., Inc. v Cree, Inc.*, 700 F.3d 1300, 1308-09 (Fed. Cir. 2012) (finding no case or controversy regarding unasserted claims where patentee narrowed asserted claims in compliance with local patent rules).

Where a case or controversy (and, therefore jurisdiction) is lacking for a counterclaim in an amended pleading, Rule 12(b)(1) authorizes dismissal of the counterclaim. Fed. R. Civ. P. 12(b)(1); *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 525 F. Supp. 2d. 680, 684 (D. Del. 2007) (“Pursuant to Federal Rule of Civil Procedure 12(b)(1), the Court is authorized to dismiss a complaint, or in this case, a [declaratory judgment] counterclaim, if the Court lacks subject matter jurisdiction over the claims alleged.”).

In compliance with the Scheduling Order in this case, Par has unequivocally advised Eagle that it is no longer asserting any claim for infringement of the Dropped Patents against Eagle. Par did not include the Dropped Patents in its final list of asserted claims and infringement contentions, and Par has agreed to stipulate to the dismissal of its infringement claims relating to the Dropped Patents with prejudice. Accordingly, there is no longer any justiciable case or controversy between Eagle and Par regarding the Dropped Patents, and all of Eagle’s counterclaims relating to the Dropped Patents should be dismissed without prejudice as moot.

III. CONCLUSION

For the reasons set forth above, Par respectfully requests that this Court grant its motion to dismiss the Mooted Counterclaims—*i.e.*, Eagle’s First, Second, Seventh, Eighth, Eleventh, Twelfth, and Sixteenth Counterclaims—without prejudice.

Dated: November 20, 2019

Respectfully submitted,

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WORD COUNT CERTIFICATION

The undersigned counsel hereby certifies that Plaintiffs' Opening Brief in Support of their Motion to Dismiss the First, Second, Seventh, Eighth, Eleventh, Twelfth and Sixteenth Counterclaims of Eagle Pharmaceuticals, Inc.'s First Amended Answer to Complaint and Counterclaims contains 1,384 words, which were counted by Brian E. Farnan by using the word count feature in Microsoft Word, in 14-point Times New Roman font. The foregoing word count does not include the cover page or the counsel blocks.

Dated: November 20, 2019

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